Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

Design

The present clinical trial includes the bioequivalence study of metformin 1000 mg tablets of Jalinous Pharmaceutical Company of Iran in comparison with metformin 1000 mg of Actover Pharmaceutical Company of Iran, after administration to 24 healthy human volunteers, in two intervention groups, in a cross-over, blinded manner. It is not done and is not random.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz company located in Mahdasht Karaj. The blinded cross-over study includes two stages (oral consumption of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Then the obtained blood samples are determined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers; Age between 18 and 55 years; non smoker; Exclusion criteria: candidates with blood pressure less than 90 on 60 mm Hg or higher than 140 on 90 mm Hg.

Intervention groups

The study includes two stages in the form of intervention 1: including the oral intake of 1000 mg metformin tablets from Iran's Jalinous Pharmaceutical Company and intervention 2: the intake of 1000 mg metformin tablets from Actover Pharmaceutical Company in Iran. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

Main outcome variables

Maximum plasma concentration of metformin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N14**
Registration date: **2024-02-27, 1402/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-27, 1402/12/08**
Update count: **0**

Registration date

2024-02-27, 1402/12/08

Registrant information

Name

Monireh Jalalipour

Name of organization / entity

Nikazma Pars Alborz company

Country

Iran (Islamic Republic of)

Phone

+98 26 3731 8748

Email address

info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

Public title
Bioequivalence study of metformin 1000 mg tablets
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer between 18 and 55 years old. Body mass index less than 30 kg per square meter. All candidates must be non-smokers.
Exclusion criteria:
Blood pressure less than 90 on 60 mm Hg or more than 140 on 90 mm Hg. Consumption of any drug, alcohol or tobacco within 2 weeks before receiving the drug.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **32**

Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2024-02-17, 1402/11/28
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.170

Health conditions studied

1

Description of health condition studied
In this research, no disease is studied.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of metformin
Timepoint
before starting to take the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours later from taking medicine
Method of measurement
Liquid chromatography - spectrophotometric detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral intake of metformin tablets of 1000 mg from Jalinous Pharmaceutical Company in Iran on 24 fasting healthy volunteers. 5 ml of blood at time intervals before starting the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours after taking the drug, it is taken from the volunteers. The cross-over study consists of two phases (oral administration of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of metformin is determined by liquid chromatography-spectrophotometry.
Category
Other

2

Description
Intervention group 2: includes the oral intake of

metformin tablets of 1000 mg of Actover Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours after taking the drug, it is taken from the volunteers. The cross-over study consists of two phases (oral administration of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of metformin is determined by liquid chromatography-spectrophotometry.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nik Azma Pars Alborz Laboratory

Full name of responsible person
Monireh Jalalipour

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

City
Mahdasht Karaj

Province
Alborz

Postal code
3188913179

Phone
+98 26 3731 8748

Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jalinous Pharmaceutical Company

Full name of responsible person
Atieh Amirpour

Street address
No. 18, 23rd St.,Kilometer 10 of Karaj special road

City
Tehran

Province
Tehran

Postal code
1399833611

Phone
+98 21 4454 3351

Email
info@jalinous.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Jalinous Pharmaceutical Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Monireh Jalalipour

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available